CLAIMS

1. A pharmaceutical composition comprising 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline or a pharmaceutically acceptable salt thereof (the Agent) and a water-soluble cellulose ether or an ester of a water-soluble cellulose ether.

2. A pharmaceutical composition according to claim 1, comprising the Agent and a water-soluble cellulose ether wherein the water-soluble cellulose ether is selected from hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose, and a water-soluble salt of carboxymethylcellulose.

3. A pharmaceutical composition according to claim 1, comprising the Agent and an ester of a water-soluble cellulose ether wherein the ester of a water-soluble cellulose ether is an ester of hydroxypropyl methylcellulose or hydroxypropyl cellulose which carries one or more ester groups selected from acetate, succinate, phthalate, isophthalate, terephthalate, and trimellitate.

4. A pharmaceutical composition according to claim 1, wherein the water-soluble cellulose ether or ester of a water-soluble cellulose ether is selected from hydroxypropyl cellulose, hydroxyethylcellulose, methylcellulose, sodium carboxymethylcellulose, and hydroxypropyl methylcellulose acetate succinate.

5. A pharmaceutical composition according to claim 1, comprising the Agent and hydroxypropyl methylcellulose.

6. A pharmaceutical composition according to claim 1, wherein the water-soluble cellulose ether is not hydroxypropyl methylcellulose.

7. A pharmaceutical composition according to claim 1, wherein the weight ratio of the Agent to water-soluble cellulose ether or ester of a water-soluble cellulose ether is from 40:1 to 2.5:1.

8. A pharmaceutical composition according to claim 1, further comprising a wetting agent.

9. A pharmaceutical composition according to claim 8 wherein the wetting agent is selected from a pharmaceutically acceptable cationic or anionic surfactant.

10. A pharmaceutical composition according to claim 8 wherein the wetting agent is an alkali metal (8-20C)alkyl sulphate.

11. A pharmaceutical composition according to claim 1, comprising the Agent, a water-soluble cellulose ether or ester of a water-soluble cellulose ether, a wetting agent, and one or more fillers, binders, disintegrants, or lubricants.

12. A pharmaceutical composition comprising:

(a) from 10 to 80 parts of 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline or a pharmaceutically acceptable salt thereof (the Agent);

(b) from 0.05 to 5 parts anionic surfactant;

(c) from 10 to 60 parts of one or more fillers selected from lactose, mannitol, and microcrystalline cellulose;

(d) from 1 to 10 parts of one or more disintegrants selected from carboxymethylcellulose sodium, carboxymethylcellulose calcium, croscarmellose sodium, crospovidone, and sodium starch glycolate ;

(e) from 1 to 20 parts of a binder selected from a polyvinylpyrrolidone and hydroxypropyl methylcellulose; and

(f) 0 to 3 parts of a lubricant;

wherein all parts are by weight and the sum of the parts (a)+(b)+(c)+(d)+(e)+(f)=100, and at least one of the components selected from (d) or (e) contains a water-soluble cellulose ether selected from hydroxypropyl methylcellulose and carboxymethylcellulose sodium.

13. A pharmaceutical composition according to claim 1, which is a solid pharmaceutical composition adapted for oral administration.

14. A solid pharmaceutical composition comprising:

(i) a core comprising 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline or a pharmaceutically[[-]] acceptable salt thereof (the Agent); and

(ii) a coating comprising an ester of a water-soluble cellulose ether or a water-soluble cellulose ether.

15. A solid pharmaceutical composition according to claim 14 which is a tablet, pellet, or granule adapted for oral administration, comprising a core coated with a film coating wherein:

the core comprises:

from 45 to 55% of the Agent;

from 25 to 40% lactose;

from 5 to 15% microcrystalline cellulose;

from 2 to 6% disintegrant;

from 1 to 5% povidone;

from 0.05 to1% sodium dodecyl sulphate; and

from 0.1 to 4% lubricant;

and wherein the film coating comprises:

from 0.5 to 3% water-soluble cellulose ether;

from 0 to 0.5% plasticiser;

from 0 to 0.5% dispersion aid;

from 0 to 0.5% opacifier; and

from 0 to 0.5% colorant;

wherein all % are by weight based upon the total weight of the composition.

16. A pharmaceutical composition according to claim 1, wherein the Agent is 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline.

17. A method of preparing a pharmaceutical composition which comprises, admixing 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline or a pharmaceutically acceptable salt thereof with a water-soluble cellulose ether and/or or ester of a water-soluble cellulose ether.

18. A method for inhibiting the rate of precipitation of the Agent from solution in the GI tract of a patient in need of the Agent, comprising orally administering to said patient a composition according to claim 1.

19. A method for reducing inter-patient variability in bioavailability and/or plasma concentrations of the Agent in a patient in need of the Agent, comprising orally administering to said patient a pharmaceutical composition according to claim 1.